DETAILED ACTION

Election/Restrictions

1. Each of the groups detailed below is drawn to multiple SEQ ID NOs. Applicant is required to elect a single SEQ ID NO for examination for a given selected group.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, 8, 9, 16 (in part) and 18 (in part), drawn to an isolated nucleic acid molecule, a vector comprising the nucleic acid, a host cell comprising the vector and a vaccine comprising the nucleic acid.

Group II, claim(s) 7, drawn to a method for determining the presence of breast specific nucleic acid (BSNA) in a sample by contacting the sample with a nucleic acid molecule according to claim 1 and detecting hybridization of the nucleic acid molecule to BSNA.

Group III, claim(s) 10, drawn to a method for producing a polypeptide encoded by nucleic acid molecule of claim 1.

Group IV, claim(s) 11, 12, 16 (in part), 18 (in part), drawn to an isolated polypeptide and a vaccine comprising the polypeptide.

Group V, claim(s) 13, drawn to an antibody or fragment thereof which specifically binds to a polypeptide of claim 12.

Group VI, claim(s) 14, drawn to a method for determining the presence of a breast specific protein in a sample, comprising the steps of: (a) contacting the sample with a suitable reagent under conditions in which the reagent will selectively interact with the breast specific protein comprising a polypeptide of claim 12; and (b) detecting the interaction of the reagent with a breast specific protein in the sample, wherein the detection of binding indicates the presence of a breast specific protein in the sample.

Group VII, claim(s) 15, drawn to a method for diagnosing or monitoring the presence and metastases of breast cancer in a patient, comprising the steps of: (a) determining an amount of: (i) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 100-253; (ii) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID

NO: 1-99; (iii)a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (i) or (ii); (iv) a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (i) or (ii); (v) a polypeptide comprising an amino acid sequence with at least 95% sequence identity to of SEQ ID NO: 100-253; or (vi) a polypeptide comprising an amino acid sequence encoded by a nucleic acid molecule having at least 95% sequence identity to a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1-99 and; (b) comparing the amount of the determined nucleic acid molecule or the polypeptide in the sample of the patient to the amount of the breast specific marker in a normal control; wherein a difference in the amount of the nucleic acid molecule or the polypeptide in the sample compared to the amount of the nucleic acid molecule or the polypeptide in the normal control is associated with the presence of breast cancer.

Group VIII, claim(s) 17, drawn to a method of treating a patient with breast cancer, comprising the step of administering a composition consisting of: (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 100-253; (b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1-99; (c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b); (d) a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (a) or (b); or (e) a polypeptide of claim 12; to a patient in need thereof, wherein said administration induces an immune response against the breast cancer cell expressing the nucleic acid molecule or polypeptide.

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: GenBank sequence with Accession No. AB017018 teaches a sequence with 100% identity to bp 1-600 of SEQ ID NO 1 (see sequence alignment), therefore it teaches a nucleic acid molecule which selectively hybridizes to SEQ ID NO: 1. Thus, the claims do not represent a contribution over the prior art and consequently lack a unifying special technical feature.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637

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